Evaluating Drug Names for Similarities: Methods and Approaches Public Meeting

(Meeting formerly called Minimizing Medication Errors - Evaluating the Drug Naming Process)

Meeting Date: June 26, 2003

The Renaissance Washington DC Hotel

At this meeting, we will explore current methods being used to evaluate proprieta drug names to reduce medication errors due to similarity in drug names. The purp of this meeting is to have an open discussion with industry, health professionals, consumers and academia on how to best minimize the potential for medication er due to similarities in proprietary drug names and will include a discussion on cur methods and approaches. We will also be soliciting feedback on a recommendati by the Department of Health and Human Services that drug manufacturers perfor proprietary name testing prior to submitting new drug applications and abbreviate new drug applications to FDA.

Meeting Date: June 26, 2003

Meeting Name: Evaluating Drug Names for Similarities: Methods and Approacl

Co-sponsored by:

- Food and Drug Administration
- Institute for Safe Medication Practices
- Pharmaceutical Research and Manufacturers Association

Location: The Renaissance Washington DC Hotel, 999 9th Street, NW, Washin D.C. 20001. (202) 962-4470.

Time: 8 a.m. - 5:30 p.m.

Agenda

Meeting Transcript [WORD] [PDF] New!! (Posted 7/8/2003)

Meeting Presentations New!! (Posted 7/15/2003)

Morning Speakers

- Five Questions, Paul Seligman, CDER
- Proprietary Names and the Drug Approval Process, John K. Jenkins, CDEI
- Look-Alike and Sound-Alike Medications Practitioner Perspectives, Timot Lesar, Albany Medical Center
- Trademark Evaluation Process: An Industry Perspective, Sharon Olmstead Pfizer
- Proprietary Name Testing Using "Prescription Analysis Studies", Thomas Hassall, Merck Research Laboratories
- Current Practices for Data Collection and Decision Analysis, Robert E. Le PhRMA Trademark Subcommittee
- Evaluating Drug Names for Similarities: Techniques and Methods Used to Collect Data and Make Decisions, James Dettore, Brand Institute, Inc.
- Responses to the Panel Moderator, Clement J. Galuccio, Interbrand Wood Healthcare
- The Med-E.R.R.S. Trademark Process, Susan Proulx, Med-E.R.R.S.
- DMETS Evaluation of Proprietary Names, Thomas (Jerry) Phillips, CDER

Open Public Hearing -- 10:45 - 11:45

Afternoon Speakers

- Sampling, Brian Strom, University of Pennsylvania, School of Medicine
- Screening Proprietary Drug Names for Similarities: Research Design and Questionnaire Structure, Shari Diamond, Northwestern University
- Evaluating Drug Names Similarities applying Handwriting Recognition Technologies, Kaz Jaszczak, Parascript, LLC
- Expert Committees , Rick Shangraw, Project Performance Corporation. (Presentation References: [WORD])
- Computational Linguistic Techniques Applied to Drugname Matching, Bo Dorr, University of Maryland
- Computer Assisted Decision Analysis in Drug Naming, Bruce Lambert, University of Illinois at Chicago
- Screening for Drug Similarities with Human Factors Engineering & Failur Mode and Effects Analysis, John Gosbee, VA National Center for Patient Safety
- Evaluating Drug Names for Similarities: Methods and Approaches, Bill Campbell, UNC School of Pharmacy

Questions: Screening Drug Names for Similarities – Methods and Approaches

1. Are methods currently employed by sponsors and FDA appropriate for evaluating look-alike and sound-alike names? Examples of methods curren being used include handwriting and voice recognition studies, computer to expert committee analyses, and questionnaire/surveys.

2. In studies designed to evaluate potential prescription errors: (a) What is an appropriate study design? (b) What is the appropriate size for an expert committee or for a prescription drug (written and voice recognition) study? What should be the composition of a group of evaluators (e.g., what propo of physicians, pharmacists, nurses, consumers)? (d) What are appropriate outcome measures?
3. What kind of information (e.g., drug name, strength, quantity, directions) should be included in verbal or handwritten prescription drug studies?
4. Sometimes similar drug names are approved contingent on a pre-marketing agreement for a risk management program. Describe examples of effective management programs (e.g., an educational campaign) that could be used t minimize look-alike, sound-alike confusion. How should the effectiveness risk management program be evaluated?
5. Should there be different trade-name evaluation procedures for different cl of drugs (prescription vs. over-the-counter)?

Minimizing Medication Errors--Methods for Evaluating Proprietary Names for T Confusion Potential; Public Meeting. *Federal Register* notice [TXT] [PDF]

Speaker Contact: Mary Gross, telephone: (301) 827-7849, fax: (301) 443-9664 grossm@cder.fda.gov

Deadline for those wishing to speak: June 13, 2003

To register to attend, please contact Elizabeth Scheiman, elizabeth.scheiman@phrma.org. Please include: name, title, company or organization, address and phone number in order to register.

Deadline for those wishing to attend: June 20, 2003

Useful Resources

USP Quality Review. March, 2001 list of similar drug names reported to the U Medication Errors Reporting Program.

Medication Errors web page. From CDER's Office of Drug Safety.

Back to Top Back to Workshops

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Evaluating Drug Names for Similarities: Methods and Approaches Public Meeting

Agenda

(Meeting formerly called Minimizing Medication Errors - Evaluating the Drug Naming Process)

Food and Drug Administration
Institute for Safe Medication Practices
Pharmaceutical Research and Manufacturers of America

Date:
June 26, 2003

Location:
Renaissance Washington D.C. Hotel, 999 9th Street, N.W., Washington, D.C. 20

Purpose of the Meeting

The FDA has determined that many of the medication errors reported to the agen result from medical products having proprietary names that look or sound like th names of other medical products. A December 1999 Institute of Medicine report (recommendation 7.3) said that FDA "require pharmaceutical companies to test (using FDA approved methods) proposed drug names to identify and remedy potential sound alike and look alike confusion with existing drug names." Subsequently, the Office of the Secretary published Recommendation #238 (fron November 21, 2002 report from the HHS Advisory Committee on Regulatory Reform). This recommendation calls for FDA to shift from doing drug name safe testing, in most cases, to reviewing data from sponsors who follow protocols designed to evaluate potential for look-alike and sound-alike errors with proprieta names prior to FDA approval. During this meeting, FDA will encourage an open public discussion with representatives from industry, health professional and consumer groups, and academia on how best to minimize the potential for medica errors due to similarities in drug names, including discussion on current methods approaches.

This public meeting is co-sponsored by FDA, the Institute for Safe Medication Practices, and the Pharmaceutical Research and Manufacturers Association. This meeting discussion will not cover other factors that may also contribute to medic errors, such as poor handwriting, incomplete patient and drug information, the us dangerous abbreviations and dose expressions, distractions in various health care settings, working conditions, and staffing conditions. The meeting will also not c the evaluation of proprietary names for their promotional implications.

Meeting Agenda

7:30 a.m. Registrant Check-In

8:00 a.m. Welcome

- Michael R. Cohen, M.S., Sc.D., President, Institute for Safe Medication Practices
- Robert E. Lee, Jr., J.D., Trademark Counsel, Eli Lilly
- Capt. Thomas G. Phillips, Associate Director for Medication Error Prevent FDA

8:15 a.m. Meeting Overview and Introduction of Questions

- Paul S. Seligman, M.D., Director, Office of Pharmacoepidemiology and Statistical Science

8:30 a.m. Perspectives on the Issue

- FDA - John K. Jenkins, M.D., Director, Office of New Drugs
- Practitioner – Timothy Lesar, Pharm.D., Director of Pharmacy, Albany Medical Center
- Industry – Sharon Olmstead, Executive Director, US Regulatory Liaison, Worldwide Regulatory Affairs, Pfizer
  Thomas Hassall, Director, Regulatory Liaison, Merck

9:10 a.m. Techniques and Methods Used to Collect Data and Make Decisions – Robert E. Lee, Jr. (Moderator)

- Brand Institute – James L. Dettore, President, Brand Institute
- Interbrand Wood – Clement J. Galluccio, Managing Director, RxMark
- Med-ERRS – Susan Proulx, Pharm.D., President, Med-ERRS
- FDA (Prescription and OTC) – Captain Thomas G. Phillips, Associate Dir for Medication Errors Prevention, Toni M. Stifano, Center for Biologics Evaluation and Research

10:15 a.m. Questions and Answers

10:30 a.m. Break

10:45 a.m. Open Public Hearing New!! (Posted 6/23/2003)

- Susan C. Winckler, RPh, JD 10:45 am - 10:52 am
  Vice President, Policy and Communications and Staff Counsel
  American Pharmacists Association
- Maury M. Tepper, III 10:52 am - 10:59 am
  Womble Carlyle Sandbridge and Rice
- Bruce L. Lambert, PhD 10:59 am - 11:06 am
  Associate Professor, College of Pharmacy, University of Illinois at Chicago
- Beston Jack Abrams 11:06 am - 11:13 am
  President, ACT, Inc.
- Suzanne Coffman, PharmD 11:13 am - 11:20 am
  Product Manager, NDC Health
- Kasey Thompson, PharmD 11:20 am - 11:27 am
  Director of Patient Safety
  American Society of Health Systems Pharmacists
- David R. Wood 11:27 am - 11:34 am
  CEO, Interbrand Wood

11:45 a.m. Lunch (on own)

12:45 p.m. Independent Experts Perspective on Data Collection Tools, – Michael Cohen (Moderator)

12:50 p.m. Sampling – Brian L. Strom, M.D., M.P.H., University of Pennsylvani School of Medicine

1:15 p.m. Questionnaire Construction – Shari Diamond, JD, Northwestern Unive School of Law

1:40 p.m. Handwriting/Voice Recognition Models – Kaz Jaszczak, Director, Proc Planning and Operations, Parascript, LLC

2:05 p.m. Questions and Answers

2:15 p.m. Break

2:30 p.m. Independent Experts Views on Decision Analysis Tools – Peter A. Gr M.D., Chairman, Internal Medicine, Hackensack University Medical Center (Moderator)

2:35 p.m. Expert Committees – R.F. Shangraw, Jr., Ph.D, Chief Executive Office Project Performance Corporation

3:00 p.m. Computer Assisted Decision Analysis

- Bonnie Dorr, Ph.D., Associate Professor, Department of Linguistics, Unive

of Maryland
- Bruce Lambert, Ph.D., Associate Professor, College of Pharmacy, Universi Illinois at Chicago

3:40 p.m. Premarketing Evaluation and Decision Analysis through Failure Mode Effects Analysis

- John Gosbee, M.D., P.E. Section Director, Patient Safety, VHA National Center for Patient Safety

4:05 p.m. Premarket Risk Management Programs

- William H. Campbell, Ph.D., University of North Carolina at Chapel Hill

4:30 p.m. Questions and Answers

4:45 p.m. Session Wrap-ups with Moderators

- Robert E. Lee, Jr.
- Michael R. Cohen
- Peter A. Gross

5:20 p.m. Closing Remarks – Captain Thomas G. Phillips, FDA

Back to Top Evaluating Drug Names

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